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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,199	12/21/2001	Claudio De Simone	2818-72	4379

7590 06/03/2003

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EXAMINER
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WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/024,199

Applicant(s)

DE SIMONE, CLAUDIO

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-11 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11 and 15-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Claims 1-11 and 15-22 are presented for reconsideration on the merits.

SEW  
5/10/3  
The amendment filed March 14, 2003, has been received and entered of record. Priority paper filed January 22, 2003, has been received. Thus, Applicants' foreign priority continues to be acknowledged and appropriate papers have been received.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

SEW  
5/10/3  
Claim 22 is objected to for the recitation of "the" before "oral cavity" and "the" should be changed to —a— or —an— to be grammatically correct.

Claims 1-11 and 15-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

The claims remain rendered vague and indefinite for failing to set forth proper antecedent basis for "component a" and "component b" in all pertinent claims where the phrases are used after their first use in claims 1 and 19. For example, in claim 1, at line 5, "wherein component (a)" is recited. The term "component (a)" as recited in line 5 is actually intended to be referring to "(a) a first component" as recited in line 2 of claim 1; thus, "wherein component (a)" really lacks antecedent basis.

Although Applicant's amendments to claims 2-3, 6, 15-16 and 18 are noted, the term —the— should at least be inserted before "component (a)" in claims 1 and 19, since it is understood that "(a) a first component" is the same as "component (a)", such change is requested unless Applicant does not intend the first component to be

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"component (a)". Likewise for the second occurrence of "component b" as used in reference to "(b) a second component" as recited in the claims. Therefore, the terms --said first-- and --said second-- or --the-- should be inserted for each of the successive repeated recitations of "component a" and "component b" at all appropriate occurrences in the claims (note also claim 1 and claim 19 and claim 10, etc.) in order that successive and further recitations of "component (a)" and "component (b)" have proper antecedent basis throughout all of the claims. Thus, this issue is maintained for these reasons and for those of record.

Claims 19-22 remain further rendered vague and indefinite for the recitation of "of prophylaxis or treating infectious" which should be changed to --of prophylaxis or treating infections--. Note that dependent claims recite "infections" and not "infectious", again this most likely is a typo in the preamble of claim 19. Note claim 21 recites "infections" in line 1.

Therefore, Applicant's arguments are not persuasive. It is suggested that Applicants closely review the claims again to make sure that consistent usage of terminology and proper antecedent basis is provided for in all of the claims.

Claims 1-11 and 15-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Cavaliere Ved. Vesely et al. (A) in view of newly cited Ehret (B) for reasons of record.

The rejection is reiterated below:

Claims are drawn to a combination of lactic acid bacteria and method of using for treating infections or inflammatory conditions.

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Cavaliere Ved. Vesely et al. (Vesely) teach a lactic acid combination which can be *Lactobacillus brevis* and *Lactobacillus salivarius*. See the abstract. The combination may be combined in various ratios and concentrations. Note col. 4, lines 10-15. At least one of the strains must have capability of producing hydrogen peroxide. Note col. 3, lines 1-15. Further, disclosed in the background art at col. 2, lines 20-30, is that various *Lactobacilli* have been used including *L. crispatus*, *L. gasseri*, *L. casei*, *L. fermentum*, etc. Further disclosed is the combination in the form of a pharmaceutical for treatment of infections such as vaginal infections. Note col. 4-5, all lines.

Ehret teaches *L. brevis* utilizes arginine. See in Table 3, in col. 8, line 61 wherein the reaction was positive for arginine.

The claims differ from Vesely in that utilization of arginine is not disclosed

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use in the combination of Vesely the *L. brevis* strain disclosed by Ehret in order to provide for a combination of the two type of *lactobacilli* which can produce hydrogen peroxide and utilize arginine. Vesely clearly teaches the treatment of infections using such combinations. To select for a lactic acid bacterium which utilizes arginine is clearly an obvious modification. This is especially true since the claimed composition is also desired to be administered orally and the arginine utilizing *L. brevis* of Ehret is disclosed to be useful in food applications. Note col. 1, line 24. One of ordinary skill in the art would have expected successful results with the combination as set forth by the Vesely and Ehret references.

The concentrations are clearly disclosed in the reference as indicated above and to vary their ratios in the composition for use in treating infections is an obvious modification as well and within the purview of an ordinary artisan. The composition is disclosed by Vesely to be applied to the vagina as an anti-inflammatory. Furthermore, to include other lactic acid producing bacteria is also clearly disclosed by the cited prior art. Formulating the composition for oral administration is clearly within the purview of an ordinary artisan and is suggested by the cited prior art combination. The combination is clearly taught by the cited prior art and one of skill would have been motivated to formulate this combination as claimed herein. In the absence of persuasive evidence to the contrary the claims are deemed *prima facie* obvious.

Applicant's arguments filed March 14, 2003, have been fully considered but they are not persuasive. Applicant's response primarily argued the secondary reference., Ehret and suggested that Vesely et al. is not a valid reference, which is the primary reference applied against the claims in the 35 USC 103 rejection. However, Vesely is a valid reference because it possesses a different inventive entity and furthermore it has a filing date of November 4, 1998, which is before Applicants' foreign priority date of June 21, 1999. Thus, the examiner fails to see how Vesely et al. is not a valid reference and therefore, the examiner maintains that Vesely is a valid reference as applied against the claims. The argument that Ehret has nothing to do with the intent of Applicant's claimed subject matter is noted, however, Ehret was applied to show that *L. brevis* utilizes arginine which Vesely et al. did not disclose. This is clearly presented as noted above in the rejection. The rejection of record clearly sets forth that Vesely et al. teach the

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combination of bacteria as claimed herein, in a method for the treatment of infections and inflammatory diseases, such as vaginal infections. Vesely et al. is not deficient in the disclosure for treatment of infections, etc.

Neither is Vesely deficient in its disclosure of a combination of bacteria as claimed herein. Vesely does not disclose one of the properties of the bacterial combination, of which is the arginine utilization by *L. brevis*. Ehret does disclose this claimed property. Therefore, to use a *L. brevis* as disclosed by Ehret is an obvious modification since it is taught by Vesely to be a desirable component of the bacterial combination as disclosed by Vesely. *L. brevis* having many array of properties are disclosed to be useful for treating infections. To select for the one disclosed by Ehret is an obvious modification and no unexpected successful result is obtained because Vesely et al. clearly teach that bacterial combinations including *L. brevis* do treat infections. To select for one *L. brevis* which utilizes arginine as disclosed by Ehret provides no unexpected successful result. Applicants have not established on the record that *L. brevis* as disclosed by Vesely do not utilize arginine. Ehret teaches that they do use arginine, although Vesely is silent about this property. Since Ehret teaches that *L. brevis* utilize arginine it may be that the *L. brevis* of Vesely utilizes arginine too and that this is an inherent property of the *L. brevis* as disclosed by Vesely.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to select for *L. brevis* since Vesely clearly teach it is useful in lactic acid bacteria combinations for treating infections. Therefore, the claims remain

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prima facie obvious over the cited prior art of record and their arguments are not deemed persuasive.

Claims 1-11, 16 and 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,277,370 (Vesely as cited above) in view of Ehret for reasons discussed above and for those of record. The examiner further fails to see how the combination is illogical and incorrect especially since the combination is disclosed by Vesely with the exception that Vesely is silent with regard to L. brevis utilizing arginine. Ehret does teach that L. brevis utilizes arginine. No unexpected successful result is obtained and Vesely motivates one of skill to select any L. brevis including those that utilize arginine. Vesely certainly does not teach against selecting L. brevis which utilizes arginine as disclosed by Ehret. Clearly one of skill would have been motivated to select L. brevis and expected successful results with the selection of L. brevis as disclosed by Ehret. The rejection is maintained and Applicant's arguments are not deemed persuasive.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Therefore, the claims are properly rejected.

No claims are allowed.

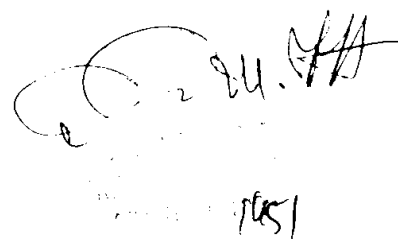
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.



Deborah K. Ware  
May 23, 2003



5-24-03